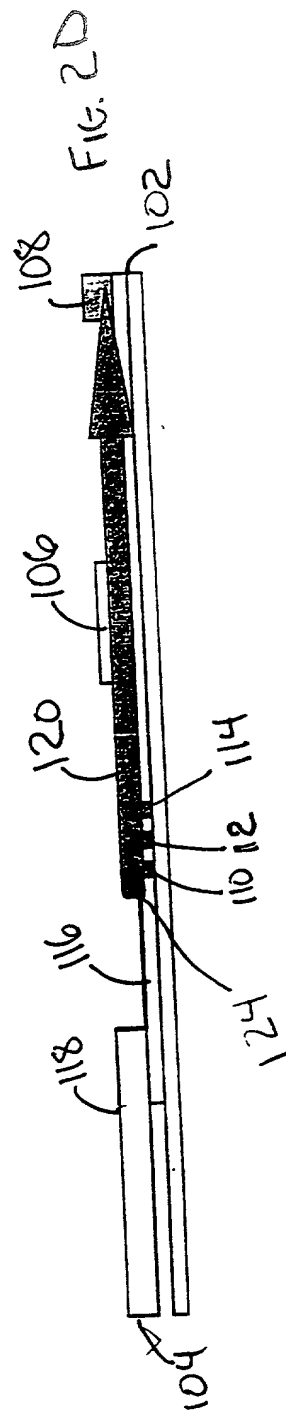
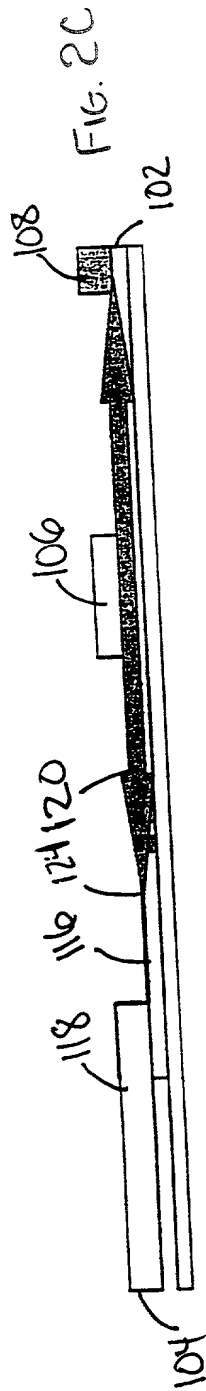
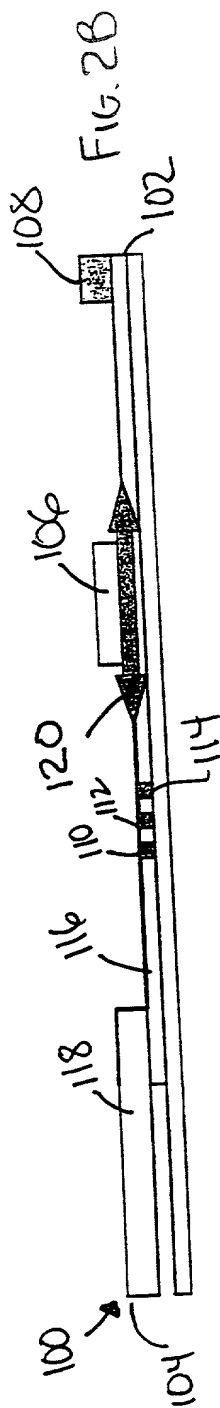
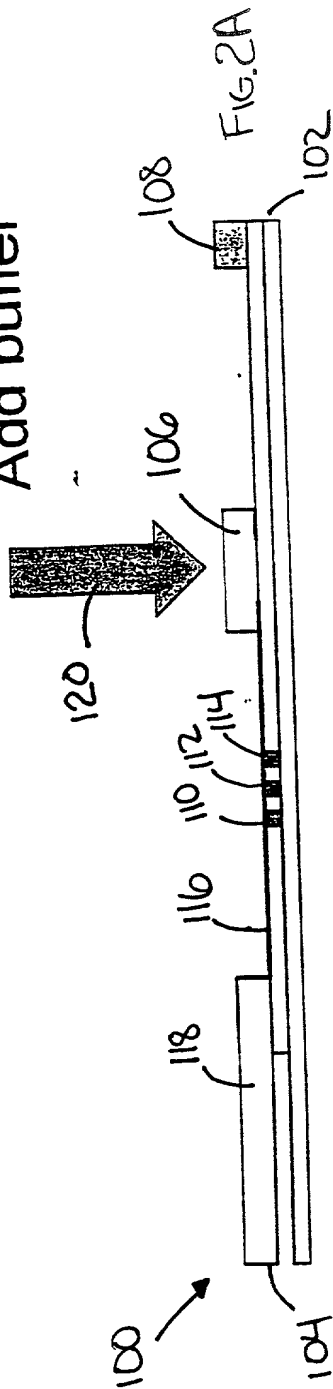


Add buffer



Add sample

Add buffer

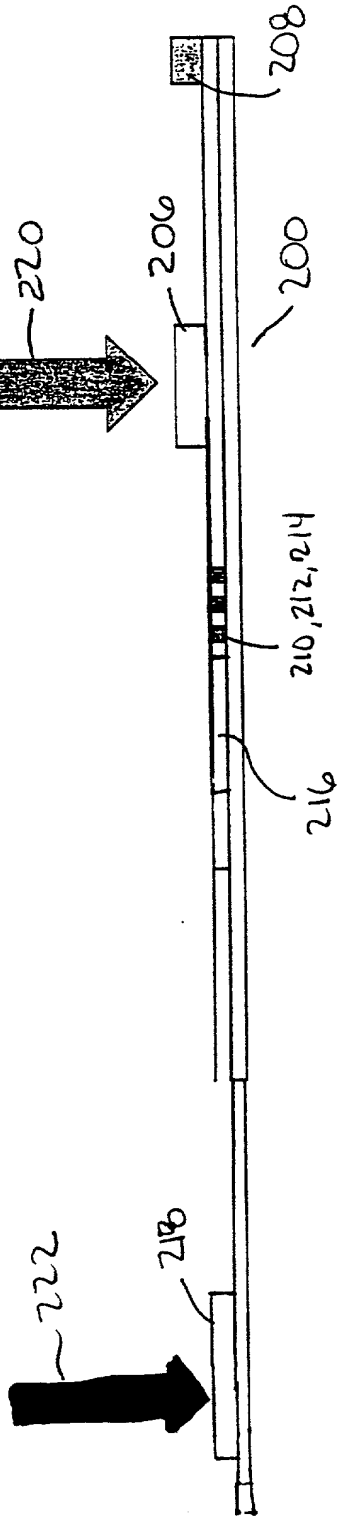


FIG. 3B

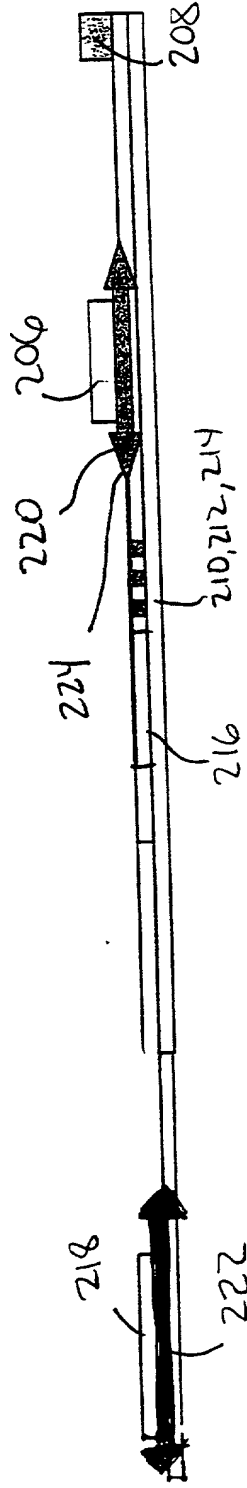


FIG. 3C

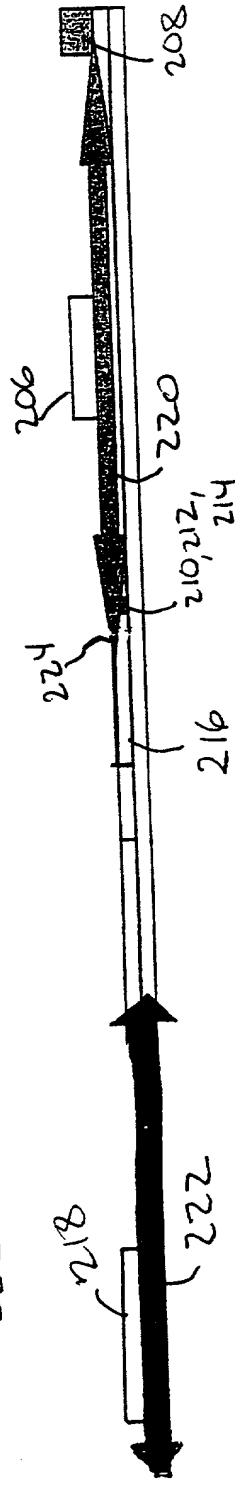
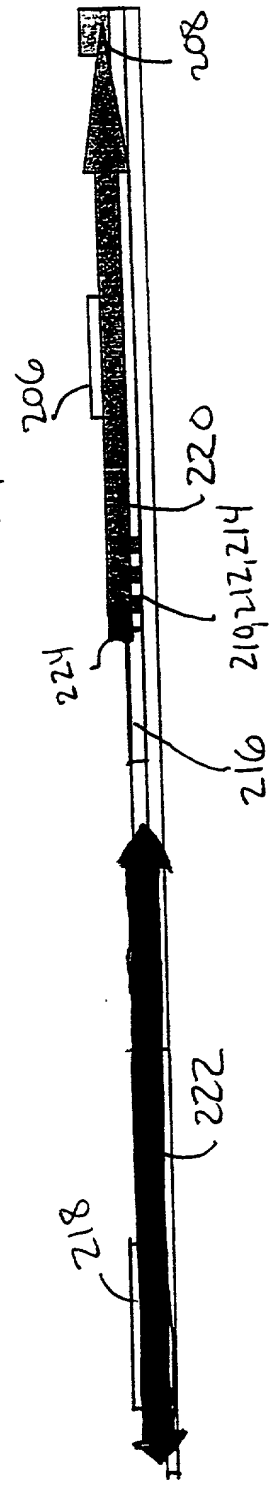
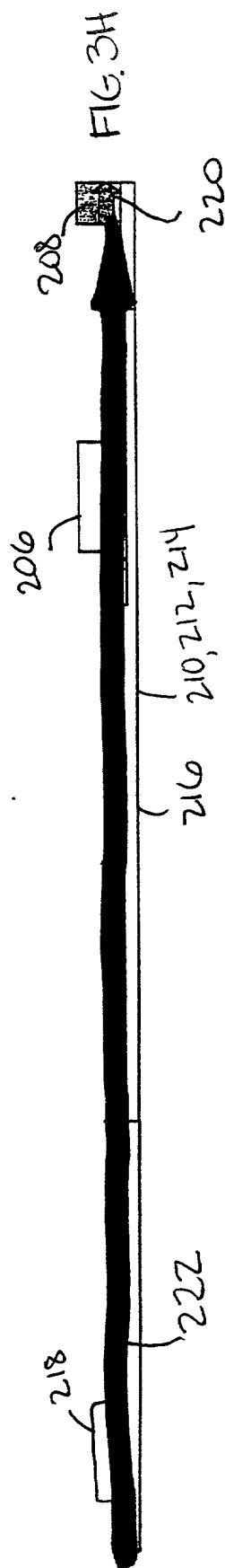
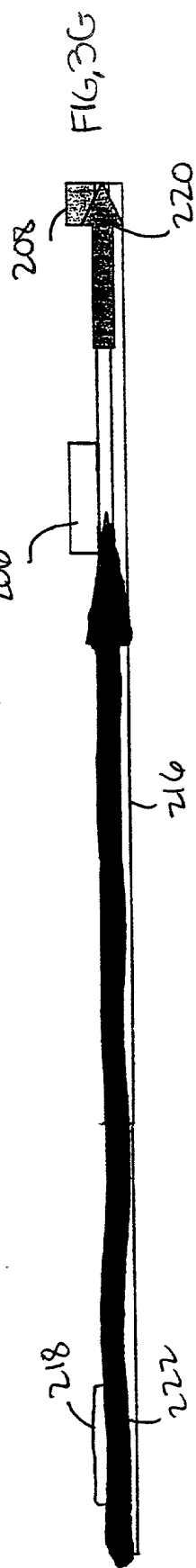
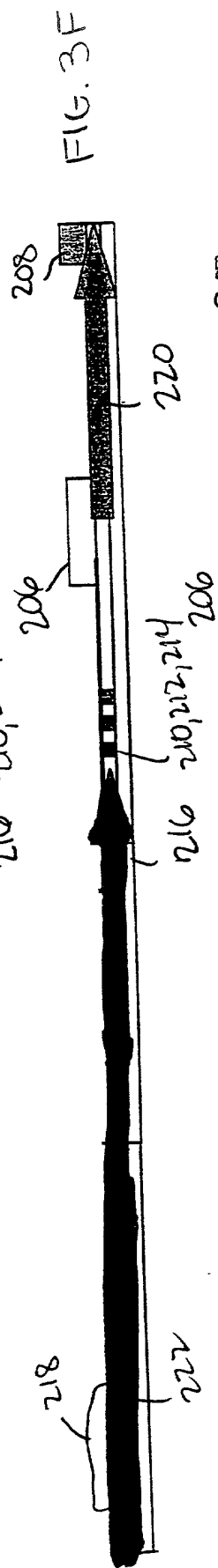
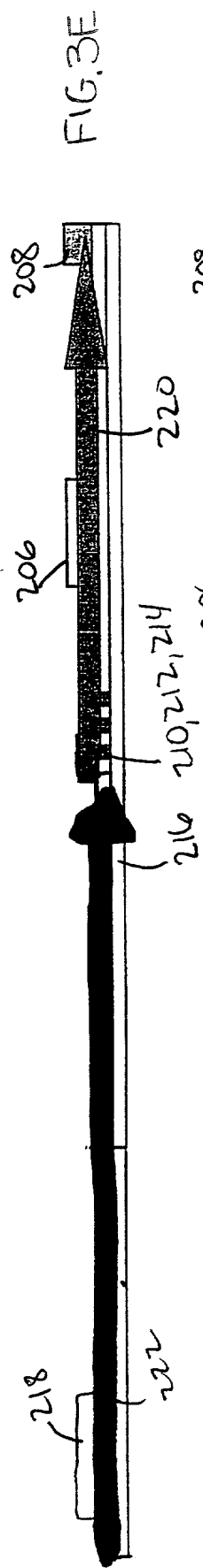
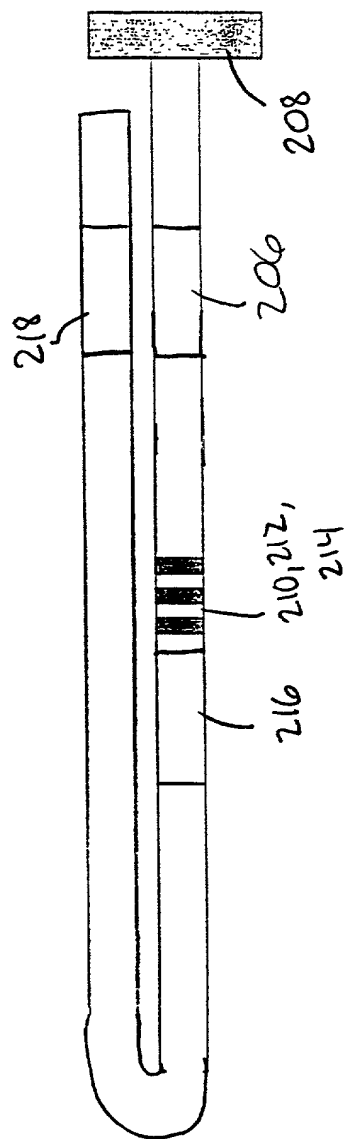
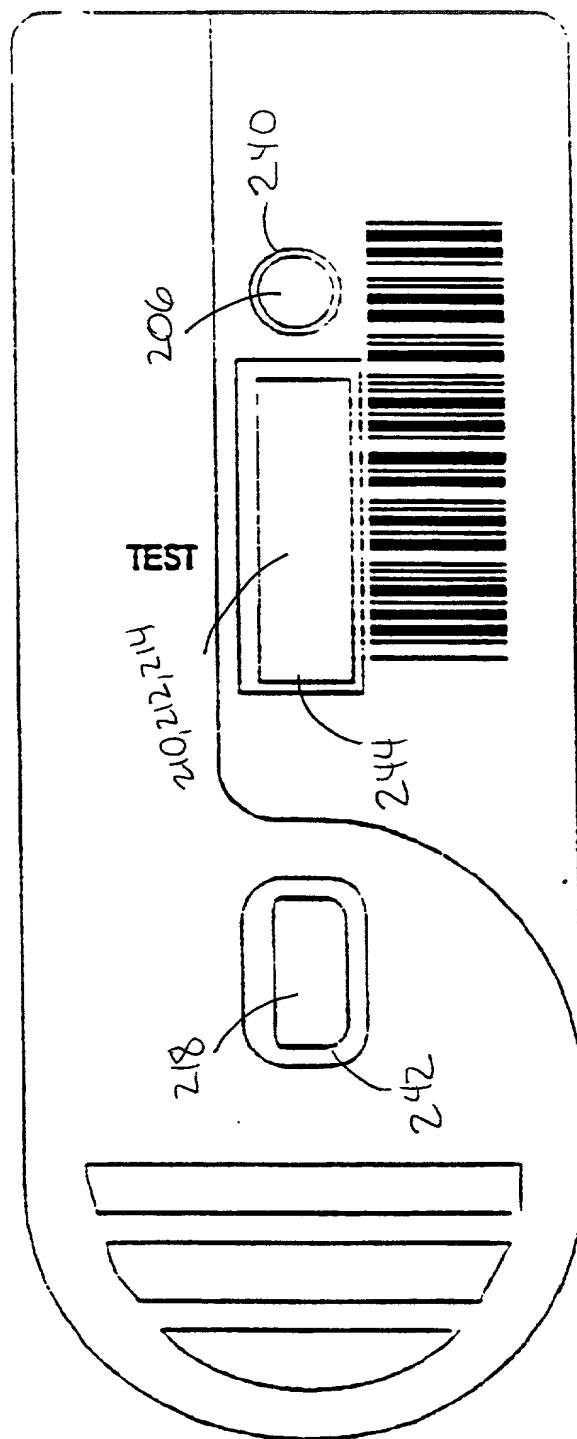


FIG. 3D









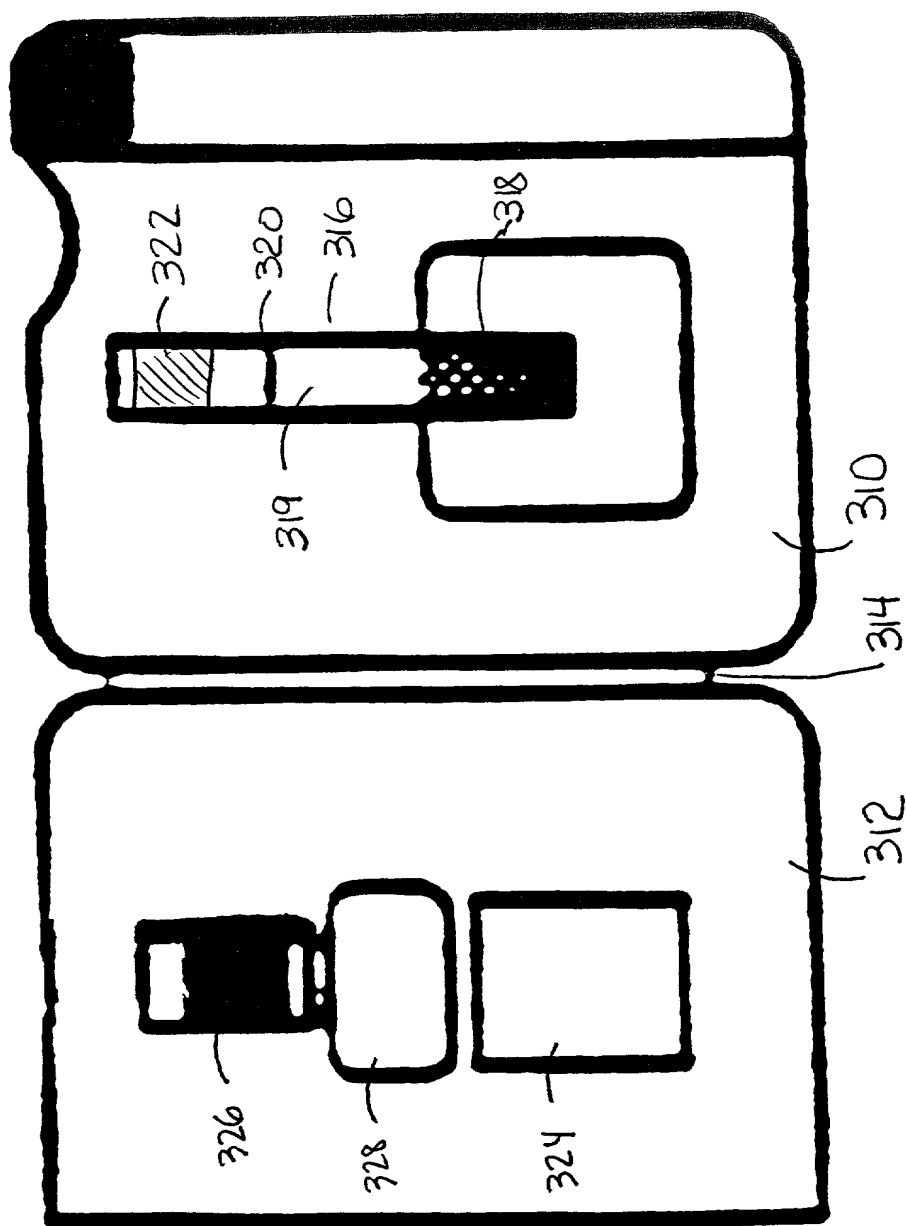
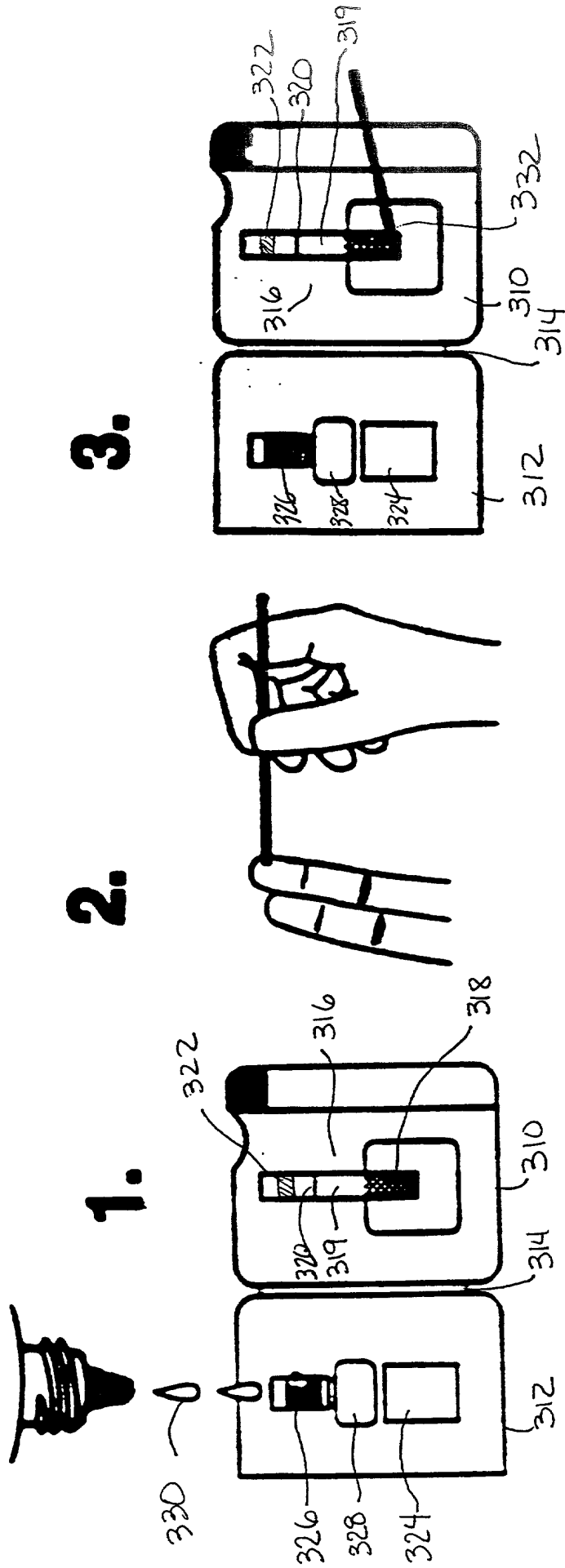


FIG. 6B



ReLIA™ TSH (Goat Capture) FIGURE 8 160 µg/ml BSA-DNP in Release Buffer

Sample	Sheet	Instrument	Hc (Dr)	Lc (Dr)	Specimen (Dr)	Hc/Lc	Specimen/HC	uIU/ml
4A	56R	104	0.3229	0.2308	0.2153	1.399	0.6667	9.21
4A	53R	120	0.3306	0.2371	0.2073	1.394	0.6270	8.48
4A	41R	110	0.3002	0.2394	0.2010	1.254	0.6695	9.26
4A	37R	163	0.3252	0.2569	0.2112	1.266	0.6496	8.89
4A	33R	115	0.2941	0.2414	0.1942	1.218	0.6605	9.08
4A	29R	107	0.3031	0.2080	0.1980	1.457	0.6532	8.95
4A	27R	146	0.3375	0.2200	0.1980	1.534	0.5867	7.74
4A	24R	111	0.3136	0.2235	0.2010	1.403	0.6410	8.72
4A	21R	104	0.2995	0.2119	0.2024	1.413	0.6755	9.37
4A	18R	120	0.3213	0.2291	0.1959	1.403	0.6097	8.16
4A	14R	110	0.2902	0.2105	0.1917	1.378	0.6607	9.10
4A	12R	163	0.3176	0.2333	0.2128	1.361	0.6699	9.27
4A	9R	115	0.3156	0.2243	0.2050	1.407	0.6494	8.88
4A	7R	107	0.3170	0.2213	0.2140	1.432	0.6751	9.37
4A	4R	146	0.3367	0.2329	0.2110	1.446	0.6265	8.46
4A	3R	111	0.3409	0.2426	0.2237	1.405	0.6562	9.01
AVG			0.3166	0.2289	0.2052	1.3856	0.6486	8.87
STD DEV			0.0158	0.0132	0.0089	0.0799	0.0250	0.46
%CV			5.0	5.7	4.3	5.8	3.9	5.2

ReLIA™ PSA (Goat Capture) 160 µg/ml BSA-DNP in Release Buffer

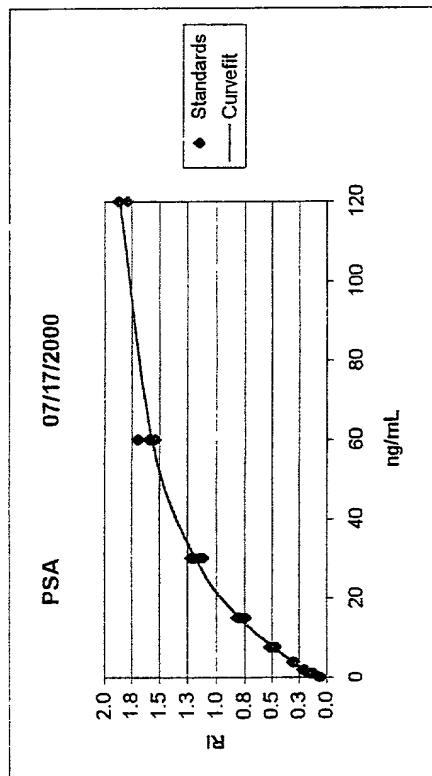
FIGURE 10

Sample	Sheet	Instrument	Hc (Dr)	Lc (Dr)	Specimen (Dr)	Hc/Lc	Specimen/HC	ng/ml
2A	HF 135-24	163	0.2438	0.2469	0.1206	0.987	0.4948	9.70
2A	HF 135-23	165	0.2243	0.2252	0.0969	0.996	0.4318	8.20
2A	HF 135-20	104	0.2883	0.2543	0.1352	1.134	0.4690	9.07
2A	HF 135-21	120	0.2188	0.2165	0.0996	1.011	0.4553	8.75
2A	HF 135-31	115	0.2448	0.2113	0.1123	1.159	0.4586	8.83
2A	HF 135-30	107	0.2301	0.2283	0.1177	1.008	0.5117	10.11
2A	HF 135-27	111	0.2149	0.1825	0.1094	1.177	0.5089	10.05
2A	HF 135-25	146	0.2329	0.2206	0.1078	1.056	0.4629	8.93
2A	HF 135-36	163	0.2907	0.2558	0.1342	1.136	0.4617	8.90
2A	HF 135-35	165	0.3104	0.2988	0.1237	1.039	0.3984	7.45
2A	HF 135-33	104	0.2467	0.2507	0.1133	0.984	0.4595	8.85
2A	HF 135-34	120	0.2424	0.2270	0.1288	1.068	0.5313	10.62
2A	HF 135-18	115	0.2535	0.2529	0.1150	1.002	0.4535	8.71
2A	HF 135-37	107	0.2784	0.2633	0.1300	1.057	0.4672	9.02
2A	HF 135-19	111	0.2702	0.2701	0.1158	1.000	0.4288	8.14
2A	HF 135-29	146	0.2624	0.2314	0.1185	1.134	0.4515	8.66
AVG			0.2533	0.2397	0.1174	1.0593	0.4653	9.00
STD DEV			0.0279	0.0275	0.0112	0.0673	0.0334	0.80
%CV			11.0	11.5	9.5	6.4	7.2	8.9

PSA

0706-HF135

Figure 11



K0	28.1760
K1	1.0984
K2	2.1378
K3	0.0764

Chi-squared

0 ng/ml	1 ng/ml	2 ng/ml	4 ng/ml	7.5 ng/ml	15 ng/ml	30 ng/ml	60 ng/ml	120 ng/ml
0.0713	0.1178	0.1927	0.3082	0.4709	0.8110	1.2190	1.5443	1.7872
0.0606	0.1126	0.1832	0.2926	0.5187	0.7819	1.1140	1.5863	1.8674
0.0641	0.1754	0.1933	0.3007	0.4582	0.7861	1.1931	1.5426	
0.0511	0.1501	0.2127	0.2891	0.5072	0.7382	1.1507	1.6945	
	0.1202							
	0.1432							

Mean	0.062	0.139	0.190	0.298	0.483	0.779	1.169	1.565	1.827
SD	0.01	0.03	0.01	0.01	0.03	0.03	0.05	0.03	0.06
CV	13.59	21.16	2.99	2.87	6.61	3.88	3.96	1.90	3.10

ng/ml	0 ng/ml	1 ng/ml	2 ng/ml	4 ng/ml	7.5 ng/ml	15 ng/ml	30 ng/ml	60 ng/ml	120 ng/ml
0.00	0.00	0.79	2.09	4.14	7.29	15.63	31.95	57.56	99.70
0.00	0.00	0.70	1.93	3.86	8.29	14.79	26.72	62.64	125.63
0.00	0.00	1.79	2.10	4.00	7.02	14.91	30.57	57.36	
0.00	0.00	1.36	2.44	3.79	8.05	13.58	28.44	79.25	

	0.00	1.12	2.04	3.95	7.53	14.73	29.42	60.10	112.66
Mean	0.00	0.42	0.10	0.15	0.67	0.85	2.31	3.59	18.33
SD	0.00	0.42	0.10	0.15	0.67	0.85	2.31	3.59	18.33
CV	0.00	37.74	4.80	3.92	8.88	5.79	7.86	5.98	16.27

FIGURE 12

Comparison of RelIA TSH Assay With Sample Added to Top and Bottom Ports Versus Sample Added to Bottom Port Only

		Sample Added to Top				No Sample Added to Top			
Sample		HCDR	Specimen DR	<u>Specimen DR</u>	TSH (uIU/mL)	HCDR	Specimen DR	<u>Specimen DR</u>	TSH (uIU/mL)
				HCDR				HCDR	
S-25 Spiked	Mean	0.2499	0.0243	0.0973	1.9088	0.204	0.0249	0.1262	2.4425
	SD	0.0154	0.017	0.0054	0.101	0.0359	0.007	0.0292	0.5276
	CV	6.2%	7.0%	5.5%	5.3%	17.6%	2.9%	23.1%	21.6%
S-42 Spiked	Mean	0.2566	0.0869	0.3399	6.2871	0.2219	0.0895	0.4055	7.4928
	SD	0.0199	0.0054	0.0275	0.4881	0.0249	0.0057	0.0281	0.5252
	CV	7.8%	6.3%	8.1%	7.9%	11.2%	6.4%	6.9%	7.0%
Pod A	Mean	0.2541	0.1369	0.5436	10.1692	0.2338	0.1394	0.6035	11.418
	SD	0.0312	0.0093	0.0497	1.0085	0.0362	0.0133	0.0575	1.4461
	CV	12.3%	6.8%	9.2%	9.9%	15.5%	9.6%	11.2%	12.7%
Pod B	Mean	0.2613	0.031	0.1186	2.308	0.2147	0.0289	0.1358	2.6254
	SD	0.0164	0.0021	0.0082	0.1526	0.0289	0.0025	0.0128	0.2336
	CV	6.3%	6.8%	6.9%	6.6%	13.4%	8.7%	9.4%	8.9%

FIGURE 13

Reproducibility of the ReLIA TSH Assay With Sample added to Top and Bottom

TSH LEVEL	ReLIA Result in uIU/mL (N = 8 Replicates)	
Normal (Approx. 1 uIU/mL)	Mean	1.0712
	SD	0.089
	CV	8.3%
Borderline Elevated (Approx. 5 uIU/mL)	Mean	6.2425
	SD	0.551
	CV	8.8%
Elevated (Approx. 25 uIU/mL)	Mean	23.631
	SD	1.658
	CV	7.0%

FIGURE 14

